

General Responses to EPA's Non-Directive Comment Key Issues on the Baseline Human Health
Risk Assessment
October 7, 2010

Issue Category	BHHRA Non-Directive Comments	General Response
Issues Needing Discussion with EPA		
Change to Exposure Scenarios	General 10, General 12(ii), 10, 45, 52, 163	<p>Exposure scenarios for the BHHRA and the approach for evaluating those scenarios were previously identified in the EPA approved (approval date of July 6, 2006) "Technical Memorandum for Human Health Risk Assessment: Exposure Point Concentration Calculation Approach and Summary of Exposure Factors (dated April 21, 2006)". In addition, the exposure scenarios were evaluated in the Round 2 Comprehensive Report without comment from EPA, or the comment was addressed in the draft BHHRA. Changes to these exposure scenarios are now being requested by EPA without information on why a change is warranted at this time. The following changes are being requested in EPA's comments:</p> <ul style="list-style-type: none"> • Evaluation of ingestion of human milk by infants for all receptors (this previously was identified as an exposure pathway for fish consumers only) • Combining adult and child scenarios • Addition of beach user exposure to groundwater seeps • Use of the 95% UCL/maximum concentration for all exposure scenarios • New child receptors: child fisher, child tribal fisher, and child consumer (it is not clear whether these are actually requests for new receptors or just a misstatement about the receptors evaluated in the BHHRA)

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Change in Dataset	32, 38, 39, 40, 54, 194	<p>The data sets used in the draft BHHRA were based on prior discussions and agreements with EPA, as documented in the Issue Resolution table for the Round 2 Comprehensive Report and the Meeting Summary Memo dated June 9, 2008. EPA is now requesting changes to those data sets. To include additional data and/or modify the data evaluated in the BHHRA would be a significant effort. The following changes are being requested in EPA's comments:</p> <ul style="list-style-type: none"> • Inclusion of data outside of the Study Area in identifying COPCs • Additional surface water data for transient and recreational beach user exposures
Clarification Needed	10, 110, 120, 159, 187	Clarification is needed from EPA.
Issues needing discussion with EPA only if EPA does not agree with our written response		
Summary of Risk Results	76, 78, 92, 97	EPA requested that a summary discussion be included at the end of the risk characterization section for each exposure medium evaluated in the BHHRA. The LWG proposes that the summary discussion should identify those chemicals with cancer risks greater than 10^{-6} , 10^{-5} , and 10^{-4} and hazard quotients greater than 1.
Carcinogenic PAHs	164	The draft BHHRA included risk estimates for both individual and total carcinogenic PAHs. The LWG agrees to add discussion of the risk results for total carcinogenic PAHs in the revised BHHRA, but does not agree that the risk results for total carcinogenic PAHs should be presented instead of individual PAHs.
Additional Language, Information, and/or Analyses Will Be Provided	65, 90, 100, 160, 167, 177, 185, 195, 196, 197, 199, 201, 206, 207, 210, 211	The LWG accepts the comment and will include additional language, information, and/or analyses in the revised BHHRA in addressing the comment.

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Probabilistic Risk Assessment (PRA)	107	The LWG agrees that the tiered approach to PRA begins with a point estimate risk assessment, which is what was done in the BHHRA. However, RAGS Volume 3 Part A clearly states "In the point estimate approach, parameter uncertainty is addressed in a qualitative manner for most variables". This is true for the BHHRA, as shown in Table 7-1 where the range of uncertainty could not be quantified for many variables. The advantages to a probabilistic risk assessment (PRA) are stated in RAGS Volume 3 Part 3 "In general, compared to a point estimate risk assessment, a PRA based on the same state of knowledge may offer a more complete characterization of variability in risk, can provide a quantitative evaluation of uncertainty, and may provide a number of advantages in assessing if and how to proceed to higher levels of analysis". The LWG believes it is important to acknowledge the limitations of the uncertainty assessment that was included in the BHHRA.
Changes to Text		
Use of the Term "Conservative"	1, 5, 175	<p>The use of the term "conservative" is consistent with EPA guidance. For example, RAGS Part A (page 6-5) states that, "The intent of the RME is to estimate a <i>conservative</i> exposure case (i.e., well above the average case) that is still within the range of possible exposures", and the EPA 2002 guidance Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites states that "the exposure point concentration (EPC) is a <i>conservative</i> estimate of the average chemical concentration in an environmental medium"</p> <p>No changes to the BHHRA are proposed by the LWG in response to these comments.</p>
Modification to Suggested Language	2, 3, 6, 50, 71, 145	EPA provided suggested revisions to the text of the BHHRA. The LWG proposes modifications to the suggested language for purposes of clarity and/or consistency.

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Description of RME Exposure Point Concentration	20, 52, 186	The draft BHHRA used the phrase "95% Upper confidence limit (UCL) or Maximum" when referring to the exposure scenario based on those exposure point concentrations (EPCs). EPA has requested that the term RME exposure be used instead. However, the exposure scenario involves multiple ingestion rates, so it is not a single "RME exposure". The LWG proposes using RME EPCs in the revised BHHRA to characterize the exposure scenario. The exposure point concentration summary tables will continue to present the basis of individual EPCs as either a UCL or a maximum.
Issues that do not need further discussion with EPA		
Risk Management Recommendations	General 9	This issue was addressed in the responses to EPA's Directive Comments.
Use of COCs in the FS and Beyond	General 7, General 9, 29, 103, 188	This issue was addressed in the responses to EPA's Directive Comments.
ARAR Evaluation in the BHHRA	General 7, 4, 8, 25, 27, 29, 31, 37, 40, 84, 118, 189, 192	This issue was addressed in the responses to EPA's Directive Comments.
Risk Driver Section in the BHHRA	General 7, 31	This issue was addressed in the responses to EPA's Directive Comments.
Changes to Text		
Deletion of Factual Statements and Comments on Remedy	7, 15, 16, 17, 21, 28, 58, 66, 74, 127, 158, 169, 183, 184, 208	This issue was addressed in the responses to EPA's Directive Comments.
Deletion of EPA Direction	11, 28	This issue was addressed in the responses to EPA's Directive Comments.
Description of Drinking Water Scenario		This issue was addressed in the responses to EPA's Directive Comments.
Characterization of Ingestion Rates	137, 139, 146, 178, 200	This issue was addressed in the responses to EPA's Directive Comments.
Deletion of Language Regarding Compounding of Conservative Assumptions	22, 81, 87, 89, 106, 175	This issue was addressed in the responses to EPA's Directive Comments.
Clam Consumption Scenario	General 2, 51, 182	This issue was addressed in the responses to EPA's Directive Comments.
Regional Tissue Concentrations	General 5, 23, 95, 168	This issue was addressed in the responses to EPA's Directive Comments.

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Agree	General 3, General 11, General 12(i), 9, 13, 18, 24, 33, 35, 47, 53, 55, 57, 59, 60, 61, 62, 67, 69, 70, 73, 77, 79, 80, 82, 86, 88, 91, 99, 104, 111, 112, 113, 114, 115, 116, 117, 119, 122, 123, 124, 129, 130, 131, 134, 135, 143, 144, 152, 153, 154, 155, 156, 157, 161, 165, 166, 172, 176, 179, 180, 181, 190, 202, 203, 204, 205, 209	The BHHRA will be revised consistent with the comment.
Other	19, 34, 42, 46, 72, 121	While the LWG believes that the language in the draft BHHRA is accurate and consistent with risk assessment guidance and disagrees that the changes requested in these comments are needed, the BHHRA will be revised per these comments.